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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,685	11/07/2000	Julio C. Palmaz	6006-015	9696

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/707,685	PALMAZ ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-53 and 67-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-53 and 67-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 39-53 have been considered however are found non-persuasive. It is first noted, that Whitcher (US 2003/0018381 A1) and Johnson et al. (US 6,533,905 B2) are both still eligible as prior art, since all independent claims 39, 47, and 67 each contain limitations not present in the priority application US 6,379,383. However, if the claims, claim 67 for instance, were written to control other properties disclosed, minus the granular precipitates, this claim would receive priority and Whitcher and Johnson in this example would not be eligible to be considered as prior art. The limitations within independent claims 39, 47, and 67, receiving the November 7, 2000 date include: "having a plurality of first structural elements defining a longitudinal axis of the stent and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent" and "formation of chemical and intra- and inter-granular precipitates" and "nickel-titanium having no less than about 51.5 atomic percent nickel". As presently written, Whitcher and Johnson do qualify as prior art.

The applicant has argued that Whitcher does not disclose a process condition "selected to control" formation of intra and inter granular precipitates, and that this property is not inherently controlled in Whitcher. The examiner disagrees. Whitcher clearly discloses precisely controlling the microstructure of a metal, see P0028, P0040. Granular precipitates are a property of the microstructure. When the microstructure is controlled, as disclosed, inherently the granular precipitates are also, since they are an element of the microstructure. Further, *process conditions* are known in the art to comprise temperature, pressure and deposition rate. For any

vacuum deposition process, a user must *select* a temperature, pressure, and deposition rate. Therefore, the user has completed the method *under process conditions selected.* What effect occurs (granular precipitates for instance) is inherently being controlled by the *selection* (that is whether there is little or a lot of precipitates changes depending on the users *selection* of the *condition*). "Selected to control" is analogous to preselected or predetermined, see 69 USPQ2d 1001, Ferguson Beauregard/Logic Controls, Division of Dover Resources Inc. v. Mega Systems LLC US Court of Appeals Federal Circuit. This rejection has been maintained.

The applicant has also argued that Johnson does not disclose a process condition "selected to control" granular precipitates. The examiner disagrees. Typical *process conditions* known in the art comprise temperature, pressure and deposition rate. For any vacuum deposition process, a user must *select* a temperature, pressure, and deposition rate. Therefore, the user has completed the method *under process conditions selected.* What effect occurs (granular precipitates for instance) is inherently being controlled by the *selection* (that is whether there is little or a lot of precipitates changes depending on the users *selection* of the condition). "Selected to control" is analogous to preselected or predetermined, see 69 USPQ2d 1001, Ferguson Beauregard/Logic Controls, Division of Dover Resources Inc. v. Mega Systems LLC US Court of Appeals Federal Circuit. This rejection has been maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-53 and 67-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitcher et al. (Pub.No. US 2003/0018381 A1, cited in previous office action). Referring to claims 39 and 67, Whitcher discloses a method of manufacturing an endoluminal stent (100) capable of radially expanding from a first diameter to a second diameter and having a plurality of first and second structural elements (fig.2), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing a stent forming metal (120) onto an unpatterned, exterior surface of a generally cylindrical substrate (105) under process conditions (temp, pressure, rate [0035, 0036, 0037]) *selected* (a temp, pressure and rate is disclosed to be selected) to control the formation of chemical and intra and inter-granular precipitates in the bulk material of a deposited tubular unpatterned metal film (115), defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate [0051, 0052, 0053]. Referring to the phrase, process condition "selected to control" granular precipitates, Whitcher discloses controlling the microcrystal structure [0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a materials microstructure. Further, inherently the precipitates are controlled, because Whitcher discloses *selection* of a process *condition*. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates is dependent upon temp, pressure, and rate, and upon selection of these elements, one has controlled the crystal structure outcome of the metal, hence the precipitates. Whitcher has

disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the *selection*. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites.

Referring to claims 40 and 68, Whitcher discloses depositing a sacrificial material layer (130) onto the substrate (105) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate [0053].

Referring to claims 41-45 and 69-72, Whitcher discloses vacuum deposition by ion beam assisted evaporation, sputtering, in the presence of an inert gas [0034, 0035, 0036, 0037].

Referring to claims 45 and 73, Whitcher discloses a deposition rate no less than 20 nm/sec ([0035], > 0.05 mm/min).

Referring to claims 46 and 74, Whitcher discloses rotation of the substrate during deposition ([0035], rotate or translate the substrate).

Referring to claim 47, Whitcher discloses a method of making an endoluminal stent (100) comprising vacuum depositing [0034, 0035, 0036, 0037] nickel and titanium [0062] onto an exterior surface of a generally cylindrical substrate (105) to form a generally tubular film of nickel-titanium having no less than about 51.5 atomic percent nickel [0066], table 1, the deposition occurring under process conditions selected to control the formation of granular precipitates in the bulk material of a deposited tubular unpatterned film, and removing the stent from the substrate [0051, 0052, 0053]. Referring to the phrase, process condition "selected to control" granular precipitate, Whitcher discloses controlling the microcrystal structure [0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since

granular precipitates are an element of a materials microstructure. Further, inherently the precipitates are controlled, because Whitcher discloses selection of a process condition. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates is dependent upon temp, pressure, and rate, and upon selection of these elements, one has controlled the crystal structure outcome of the metal, hence the precipitates. Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the *selection*. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites.

Referring to claims 48, 50, and 51, Whitcher discloses a nickel-titanium composition between *about* 51.5 and 55.0 atomic percent nickel, wherein the nickel and titanium is a binary nickel-titanium alloy (table 1), [0062, 0066].

Referring to claim 49, Whitcher discloses the rotation of the substrate during deposition (vector A, [0048]).

Referring to claims 52 and 53, Whitcher discloses imparting a pattern onto the exterior surface of the substrate (105), wherein the pattern is transferred to the film during deposition [0055, 0056], and alternatively, imparting a pattern onto the tubular film after deposition [0054].

Claims 39-40, 42, 46-53, 67-68, 70, and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. (USPN 6,533,905 B2, cited in previous office action). Referring to claims 39 and 67, Johnson discloses a method of manufacturing an endoluminal stent capable of

radially expanding from a first diameter to a second diameter and having a plurality of first and second structural elements (fig.9; col.1, lines 10-15), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing (col.4, lines 52-53; col.5, lines 19-20) a stent forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate (10; col.3, lines 62-67) under process conditions that are selected to control the formation of chemical inter and intra-granular precipitates in the bulk material of a deposited generally tubular, unpatterned metal film, defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate (col.4, lines 21-31; col.5, lines 62-67). Referring to the phrase process conditions "selected to control" granular precipitates, it is noted to the applicant that all the applicant has claimed here is a **process condition selection**. Every condition is a variable, such as deposition rate, temperature, pressure, choice of material, etc, and each condition/variable will have an effect on the crystal structure upon *selection*, such as grain size or granular precipitates of the material. Because Johnson has disclosed a temperature, pressure, and specific material composition, the properties of the material are *preselected* and are being *controlled*. The applicant has only a condition selected, and during deposition, a *condition* is always selected. Also, every metal has a specific grain size, grain phase, granular precipitates, composition, and binding sites, and just by the user selecting a specific material, the user is controlling such elements.

Referring to claims 40 and 68, Johnson discloses depositing a sacrificial material layer (14) onto the substrate (10) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate (col.4, lines 24-31).

Referring to claims 42 and 70, Johnson discloses vacuum deposition by sputtering (col.5, lines 25-29).

Referring to claims 46 and 74, Johnson discloses rotation of the substrate during deposition (col.4, lines 48-53).

Referring to claim 47, Johnson discloses a method of making an endoluminal stent (fig.9) comprising vacuum depositing nickel and titanium (col.4, lines 54-65; col.3, lines 25-29) onto an exterior surface of a generally cylindrical substrate (10) to form a generally tubular film of nickel-titanium having no less than about 51.5 atomic percent nickel (col.4, lines 54-65; col.3, lines 25-29; col.5, lines 1-13) wherein the deposition is under process conditions selected to control the formation of chemical inter and intra-granular precipitates in the bulk material (it is noted to the applicant that all the applicant has claimed here is a **condition selection**. Every condition is a variable, such as deposition rate, temperature, pressure, choice of material, etc, and each condition/variable will have an effect on the crystal structure, such as grain size or granular precipitates of the material. Because Johnson has disclosed a temperature, pressure, and material composition, the properties of the material are *preselected* and are being *controlled*. The applicant has only a condition selection, and during deposition, a *condition* is always present and selected. Also, every metal has a specific grain size, grain phase, granular precipitates, composition, and binding sites, and just by the user selecting a specific material, the user is controlling such elements) and removing the stent from the substrate (col.5, lines 62-67).

Referring to claims 48, 50, and 51, Johnson discloses a nickel-titanium composition between about 51.5 and 55.0 atomic percent nickel, wherein the nickel and titanium is a binary nickel-titanium alloy (col.4, lines 54-65; col.3, lines 25-29; col.5, lines 1-13).

Referring to claim 49, Johnson discloses the rotation of the substrate during deposition (col.4, lines 48-53).

Referring to claims 52 and 53, Johnson discloses imparting a pattern onto the exterior surface of the substrate (col.6, lines 36-50), wherein the pattern is transferred to the film during deposition, and alternatively, imparting a pattern onto the tubular film after deposition (col.6, lines 19-22).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER